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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,346	01/14/2004	Heinrich Kladders	01-1447	3492
28501 7590 06/23/2008 MICHAEL P. MORRIS BOEHRINGER INGELHEIM USA CORPORATION 900 RIDGEBURY ROAD P. O. BOX 368 RIDGEFIELD, CT 06877-0368				
EXAMINER				
MATTER, KRISTIN CLARETTE				
ART UNIT		PAPER NUMBER		
3771				
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06/23/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/757,346

Applicant(s)

KLADDERS ET AL.

Examiner

KRISTEN C. MATTER

Art Unit

3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Action is in response to the request for continued examination submitted on 5/9/2008. Claim 1 was amended and no claims were added or cancelled. Currently, claims 1-10 are pending in the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hochrainer et al. (US 5,947,118) in view of Datta et al. (US 5,871,010) and further in view of Bartels et al. (US 5,472,143).

As to claims 1 and 5, Hochrainer et al. disclose an inhaler for the administration of a pharmaceutical composition comprising a mouthpiece (12), an air channel opening into the mouthpiece and a chamber (9) with an air inlet channel wherein the inhaler is capable of receiving a capsule with a composition (see Figure 6). Hochrainer et al. does not disclose at least part of the inner surface of the mouthpiece and/or of the air channel and/or optionally the chamber contains elevations and/or depressions with a height/depth of from 0.1 to 100 microns. However, Datta et al. teach an inhaler apparatus with a modified surface for enhanced release of dry powders. Datta et al. disclose the surface of the substrate and the mouthpiece as having elevations and depressions with a depth of one micron to about 2.5 microns (column 2, lines 15-

44), which meets the claimed range of 0.1 to 100 microns. Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of Hochrainer et al. with the depressions taught by Datta et al. in order to decrease the area of contact between the selected medicaments so that medicament particles do not stick to the inside surface of the mouthpiece. In addition, the only difference between the depressions of Datta et al. and the instant application is the shape (i.e., sloped and/or tapered parabolic-shaped versus parallel grooves). Absent a critical teaching and/or a showing of unexpected results from making the depressions sloped/tapered shaped, Examiner contends it is an obvious design consideration to one of ordinary skill in the art to make the depressions grooves or egg-carton shaped as a matter of manufacturing preference because sloped/tapered is a well known shape. Furthermore, because the grooves of Datta et al. are provided to minimize the area of contact in order to maximize the release of medicament (column 2, lines 25-30 and column 7, lines 55-60), it appears as though the modified device would perform equally well with sloped/tapered depressions as opposed to parallel grooves. See also *In re Dailey*, 357 F.2nd 669, 149 USPQ 47 (CCPA 1966), in which the court upheld that changes in shape without a change in function do not patentably distinguish a claimed invention over the prior art. To the extent that the modified Hochrainer and Datta et al. reference is silent as to the process for forming the elevations/depressions Bartels et al. disclose an atomizing nozzle for use in an inhaler in which the depressions forming the nozzle outlets are formed from well-known microforming techniques including chemical etching, laser, photo-resist, or other engraving techniques (column 4, lines 10-25). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used chemical etching (a microtechnology and subtractive

treatment), for example, to produce the depressions in the modified device of Hochrainer et al. and Datta et al. in order to produce readily reproducible and accurate depressions in the mouthpiece on a micro-scale.

As for claim 2, Datta et al. is silent as to the percentage of the interior surfaces having depressions. However, it would have been an obvious design consideration to one of ordinary skill in the art at the time the invention was made to have used microtechnology to produce depressions over at least 20% of the inner surfaces in order to deliver a maximum amount of medicament to the user without having the particles stick to the inside surfaces of the inhaler.

As for claim 3, Datta et al. disclose the elevations and depressions are separated by spacings of 2 microns, which reads inside the range from 0.1 to 200 microns.

As for claim 4, Datta et al. has taught an inhaler with inner surfaces being made with polycarbonate (column 7, line 65), for example, which is one of the claimed materials.

As for claims 6 and 7, Hochrainer et al. inherently disclose a Bernoulli inhaler. In addition, the applicant has admitted that Bernoulli inhalers are prior art (paragraph 3, lines 4-7). Hochrainer et al. disclose the inhaler comprising a capsule chamber (9), which is connected to the air channel opening in the mouthpiece.

In regards to claims 9 and 10, Hochrainer et al. disclose the inhaler as having a cutting device, which is fitted with at least two sharp spikes, the spikes are capable of being inserted through openings into the capsule chamber (column 3, lines 5-9). Hochrainer et al. continue to disclose an inhaler comprising a cup-shaped lower part 6 open at the top, a plate (8) that covers the opening of the lower part (6) and perpendicularly to which is formed the capsule chamber, a button (10) movable counter to a spring on the capsule chamber, comprising two sharp spikes for

opening the capsule, an upper part (13) with the mouthpiece (12) and the air channel which connects the mouthpiece (12) to the capsule chamber (9) so as to be able to convey a powder or liquid or aerosol, and a lid, these elements being joined together by a common hinge element such that they can be moved back and forth relative to one another (column 3, lines 15-18).

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hochrainer et al. and Datta et al. and Bartels et al. and further in view of Kladders (US 4,889,114). The modified Hochrainer et al. reference has disclosed everything except the capsule chamber as having a diameter 1.1 to 2.5 times the capsule diameter and a length 1.02 to 2 times the length of the capsule. However, Hochrainer et al. has taught that the capsule chamber needs to have a diameter large enough to hold the capsule (column 1, lines 19-21). In addition, Kladders discloses a similar powder inhaler with a capsule chamber (6) with a diameter 1.1 to 2.5 times the capsule diameter and a length 1.03 to 2 times the length of the capsule (column 2, lines 10-19). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the device of Hochrainer et al., Datta et al., and Bartels et al. with the capsule chamber diameter and length as taught by Kladders so that the capsule fits in the chamber in order to be more effective during delivery for inhalation.

Response to Arguments

Applicant's arguments filed 5/9/2008 have been fully considered but they are not persuasive.

In response to applicant's arguments that the Datta et al. reference does not disclose sloped/tapered depressions, examiner contends that although Datta et al. teaches parallel grooves for the depressions/elevations that does not imply that Datta et al. teaches away from other well known shapes such as a sloped/tapered shape. Case law was cited in the rejection to demonstrate the obviousness of changes in shape, and without a critical teaching and/or a showing of unexpected results from the sloped/tapered shaped depressions, it appears as though the device would perform equally well with any shape of depressions inasmuch as the surface area of contact between the medicament and the surface walls was reduced (as compared to the flat surface wall without depressions). Examiner also wishes to point to page 9, line 20 of the instant specification in which various other shapes (as opposed to just sloped/tapered shapes) are disclosed for the depressions, implying that the sloped/tapered shaped of the instant invention is not a critical feature. Again, as mentioned above, mere changes in shape do not patentably distinguish the invention over the prior art.

In response to applicant's argument involving the contact area between sloped/taped depressions versus parallel grooves (as accompanied by the submitted Figure on 5/9/2008), examiner argues that the teaching of Datta et al. for "minimizing the area of contact between the medicament and the surface" is in comparison to a flat surface with no grooves (see column 2, lines 15-30, column 5, lines 20-40, and column 5, line 65-column 6, line 15). The fact that parallel grooves would have a smaller contact area as compared to the sloped depressions in the submitted Figure does not imply that Datta et al. teaches away from sloped/taped depressions. Sloped/taped depressions would provide a smaller area of contact as compared to a flat surface without grooves. Therefore, so long as the parallel grooves or sloped/tapered shape were of an

appropriate size as compared to the particle size of the medicament, the surface area of contact would be reduced as taught by Datta et al. and the device of Datta et al. would perform equally well.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen C. Matter whose telephone number is (571) 272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771

/Kristen C. Matter/
Examiner, Art Unit 3771